

Question and Answers

42 CFR Part 93

These questions and answers are intended to: (1) Assist institutional research integrity officers (RIOS), compliance officers, institutional counsel, and other institutional officials in understanding the obligations of institutions under the new regulation, to be codified at 42 Code of Federal Regulations (CFR) Part 93; (2) Assist PHS funded researchers and respondents, complainants, witnesses and other involved parties in understanding how the regulation affects them; and (3) Provide information about the new regulation to interested members of the public. For ease of reference, the answers refer to the pertinent section or sections of the regulation.

Q: When did the new regulation become effective?

A: The final rule became effective on June 16, 2005, 30 days after the date of its publication in the Federal Register (70 FR 28370). For any allegation received on or after June 16, 2005, the institution must comply with the new regulation.

Q: Does the final rule apply retroactively?

A: No, the final rule applies prospectively. The effect of that prospective application will depend upon how the provisions of the rule interact with the activities of the institution and ORI. Upon its effective date the final rule will apply to institutions that are receiving PHS support for research, research training, or activities related to that research or research training. For institutions not receiving such PHS support, the regulation will not apply until they submit an application for PHS support.

Generally, if an institution has a research misconduct proceeding pending at the time the new regulation becomes effective, ORI would expect the new procedural requirements to be applicable to the institution's subsequent steps in the proceeding, unless the institution or respondent would be unduly burdened or treated unfairly. However, the definition of research misconduct that was in effect at the time the alleged misconduct occurred would apply. If an institution to which the final rule applies on the effective date has completed an inquiry and investigation and reports to ORI after the effective date of the final rule, ORI will take further action, make findings, and provide an opportunity for a hearing in accordance with the final rule. If a request for a hearing is received by the DAB Chair after the effective date of the final rule, the hearing will be conducted in accordance with the final rule. This will ensure that respondents have the benefit of the detailed, fair hearing procedures in the final rule.

Because it is not possible to address every possible scenario relating to the prospective application of the final rule, institutions that have received allegations of misconduct, or have ongoing inquiries or investigations upon the effective date of the final rule should contact ORI to determine how the rule will apply to those ongoing activities. ORI will make every effort to minimize burdens and ensure that all parties are treated fairly.

Q: What will an institution be expected to do upon the effective date of the final rule?

A: As soon as practical after the effective date of the final rule, institutions should bring their policies and procedures into compliance with the new regulation.

Primary Changes from Old Rule

Q: What are the primary differences between the new regulation, 42 CFR Part 93 and the old regulation, 42 CFR Part 50, Subpart A, regarding the policies on research misconduct?

A:

- **Applicability.** The new rule includes PHS intramural research programs and contracts that support research, research training or activities that are related to research or research training. The new rule applies to an allegation that PHS-supported research involving journal peer review has been plagiarized. Section 93.102.

- **Limitations period.** Because of the problems that may occur in investigating older allegations and the potential unfairness to the respondent in defending against them, the new rule is limited to research misconduct occurring within six years of the date on which HHS or the institution receives the allegation of misconduct, unless: (1) the respondent continues or renews any incident of alleged research misconduct that occurred outside the six-year limit through the citation, republication or other use for the potential benefit of the respondent of the research record that is the subject of the allegation; (2) ORI, or the institution, following consultation with ORI, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public; or (3) if HHS or the institution received the allegation before the effective date of the new rule. Section 93.105

- **Definition of Research Misconduct.** Consistent with the Office of Science and Technology Policy (OSTP) government wide definition and guidelines on research misconduct, the new rule uses the term “research misconduct” rather than “misconduct” or “misconduct in science” and, among other changes, defines this term to include a new element: misconduct occurring in connection with the “reviewing” of research. The “other practices” part of the existing definition has been dropped. Section 93.103. Falsification, fabrication, and plagiarism have also been separately defined.

- **Burden of Proof.** Consistent with the OSTP guidance that the exclusion of honest error or difference of opinion from the definition of research misconduct does not require HHS and the institutions to disprove possible honest error or difference of opinion, the new rule provides that these elements are an affirmative defense that the respondent has the burden of proving by a preponderance of the evidence. However, the institutions and HHS retain the burden of proving research misconduct by a preponderance of the evidence and any admissible, credible evidence the respondent submits to prove honest error or difference of opinion must be weighed in determining whether the institution and HHS have carried this burden. Sections 93.106(b)(1) and (2) and 93.516(b).

- **Institutional Responsibilities.** The new rule describes in greater detail the responsibilities of the institutions in responding to allegations of research misconduct. Institutions must take certain steps to ensure a fair and thorough investigation, such as securing the evidence and giving the respondent opportunities to access the evidence and comment on the investigational report. In addition, the new rule provides greater detail on ORI’s oversight of the institution’s investigation or other misconduct proceeding and the actions that ORI may take if an institution fails to comply with the rule. Specific institutional responsibilities are addressed in the Qs & As that follow. Subpart C, Sections 93.300 - 93.319.

- **Hearing Process.** The new rule sets forth a detailed hearing process that is modeled on the HHS Office of Inspector General (OIG) regulation, 42 CFR part 1005, that governs the hearing process for the exclusion of health care providers from Medicare and State health care programs. Among the changes from the current ad hoc hearing process is that the trier of fact will be an Administrative Law Judge, rather than a three-person panel of the Departmental Appeals Board (DAB). Subpart E, Sections 93.500 - 93.523.

• **Responsibilities of ORI and the ASH.** The new rule changes the respective responsibilities of ORI and the Assistant Secretary for Health (ASH). The ALJ's findings of fact and conclusions of law constitute a recommended decision to the Assistant Secretary for Health (ASH). Under the final rule, the ASH may let the ALJ's recommended decision stand, or take final agency action, exercising authority to affirm, reverse, or modify the ALJ's recommended decision, if it is found to be arbitrary and capricious, or clearly erroneous. If debarment or suspension from eligibility for Federal financial assistance and/or contracts is proposed, the decision of the ALJ or of the ASH, as the case may be, constitutes proposed findings of fact to the HHS Debarment Official. If the ASH takes final action on the ALJ's recommended decision and the Debarment Official concurs, the ASH decision constitutes final agency action. Section 93.523. In order to ensure a separation of this ASH responsibility from the responsibility of making a finding of research misconduct, ORI will propose initial findings of research misconduct, subject to the DAB hearing process, and recommend settlements to HHS. This change will maintain the separation between investigation and adjudication, because ORI will not conduct any inquiry or investigation on behalf of HHS. There will rarely be a need for HHS, rather than an institution, to conduct an inquiry or investigation, but if it is necessary, the OIG would carry out that responsibility. Sections 93.400, 93.404, 93.500, and 93.523.

Q: In what way is the applicability of the new regulation more narrow than the current regulation, policies and practices?

A: The scope of the new regulation is limited to cases in which the alleged research misconduct occurred within 6 years of the date HHS or an institution receives an allegation of research misconduct. With some exceptions, no inquiry or investigation under the regulation may proceed where the alleged misconduct occurs outside this 6 year limitation period. This standard is modeled after the limitation period used in the qui tam provision of the False Claims Act and after the procedures used by the HHS Office of the Inspector General in its Medicare and Medicaid exclusion cases.

Finding Research Misconduct

Q: What is research misconduct?

A: Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Research misconduct does not include honest error or differences of opinion. Section 93.103.

Q: Does plagiarism include disputes about authorship or credit among collaborators?

A: No. In keeping with PHS and OSTP policies, such disputes are not included in the definition of research misconduct in the new regulation, as explained in more detail in the preamble of the Notice of Proposed Rulemaking (69 FR 20778, 20780 April 16, 2005). Also, see ORI's policy statement on plagiarism at <http://ori.dhhs.gov/policies/plagiarism.shtml>

Q: What is necessary for a finding of research misconduct?

A: (1) There must be a significant departure from accepted practices of the relevant research community.

(2) The misconduct must have been committed intentionally, knowingly, or recklessly.

(3) The allegation must be proven by a preponderance of the evidence. Section 93.104.

Q: What is a preponderance of the evidence?

A: A preponderance of the evidence means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not. Section 93.219.

Q: Whom has the burden of proving research misconduct?

A: The institution or HHS has the burden of proving research misconduct. Section 93.106(b)(1). However, the respondent must prove by a preponderance of the evidence that honest error or difference of opinion occurred. In determining whether HHS or the institution has carried its burden of proving research misconduct, the finder of fact must give due consideration to admissible, credible evidence of honest error or difference of opinion presented by respondent. Section 93.106(b)(2).

Q: Is the destruction, absence of, or the respondent's failure to provide research records adequately documenting the research that is the subject of an allegation of research misconduct evidence of research misconduct?

A: Yes, if the institution or HHS establishes by a preponderance of the evidence that: (1) the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner; and (2) the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community. Section 93.106(b)(1).

Institutional Responsibilities

Assurances and Administration

Q: In general, what must institutions do to comply with the new rule?

A: The responsible institutional official for each institution that applies for or receives PHS support for biomedical or behavioral research, research training, or activities related to that research or research training must assure that the institution: (1) has written policies and procedures, in compliance with the rule, for inquiring into and investigating allegations of research misconduct; (2) complies with those policies and procedures; and (3) complies with the requirements of the rule. Section 93.301.

ORI considers an institution to be in compliance with its assurance if the institution: (1) Establishes the required policies and procedures, keeps them in compliance with the rule, and provides them to ORI and to other authorized HHS personnel, upon request; (2) Takes all reasonable and practical steps to foster a research environment that promotes the responsible conduct of research, discourages research misconduct, and responds promptly to allegations or evidence of possible research misconduct, including the specific steps of complying with its policies and procedures and informing its research members involved with PHS supported research of those policies and procedures and its commitment to compliance with them; (3) Submits an annual report to ORI that contains information specified by ORI on the institution's compliance with the rule; and, (4) Upon request, provides to ORI with its assurance or annual report such other aggregated information as ORI may request on the institution's research misconduct proceedings and compliance with the rules. Section 93.302.

Section 93.304 sets forth what the institutional policies and procedures must include.

Q: What if the awardee institution for PHS research funds is a cooperative clinical group (or other research group or an institution with subcontractors) and some misconduct is alleged at one of the other members of the groups or a subcontractor - who is supposed to conduct the inquiries and investigations and report to ORI?

A: "The Public Health Service Policies on Research Misconduct at 42 CFR Part 93 do not directly address this issue. Section 93.214 defines "institutional member" to include contractors, subcontractors, and subawardees and their employees. Section 93.300(f) requires institutions to take all reasonable and practical steps to ensure the cooperation of institutional members with research misconduct proceedings, but neither that section nor any other section addresses who is responsible for conducting research misconduct proceedings if the misconduct is alleged against an employee of a contractor or subawardee of a grantee institution.

The NIH Grants Policy Statement provides, in its discussion of Public Policy Requirements and Objectives, that the grantee is responsible for establishing and maintaining the necessary process to monitor its compliance and that of its employees, consortium participants and contractors with the requirements of the grant. The grantee is responsible for compliance with its research misconduct assurance for all awarded funds, including those made available to subawardees and contractors. In order for a grantee to meet its responsibility, the contract or subaward must bind the contractor or subawardee and its employees to comply with the requirements of the PHS Policies on Research Misconduct and provide how an allegation of research misconduct involving one of those employees will be handled. The contractor or subawardee may be in a better position to carry out inquiries and investigations, because they have control over the respondent and the pertinent records. However the grantee institution must also consider whether the contractor or subawardee has the resources and capability to carry out inquiries and investigations. If the grantee institution determines that contractor or subawardee does not have the ability to promptly carry out inquiries and investigations in accordance with the PHS Policies, it should take that responsibility or utilize the services of a consortium or other qualified person in accordance with Section 93.306.

Grantee officials involved in cooperative groups or other contractor or subawardee arrangements are encouraged to talk to ORI Staff about such matters (phone 240-453-8800), as well as report to the central group and to any federal or other monitoring groups as appropriate when issues of discrepancies in cooperative group trial records arise.

Q: Is there an exception from the assurance requirements for small institutions?

A: Yes, a limited exception. If an institution is too small to handle research misconduct proceedings, it may file a "Small Organization Statement" with ORI in place of having written policies and procedures for addressing research misconduct. By submitting that statement the institution agrees to report all allegations of research misconduct to ORI. ORI will work with the institution to develop and implement a process for handling allegations of research misconduct in a manner that is consistent with the rule. The Small Organization Statement does not relieve the institution from complying with any other provision of the rule. Section 93.303.

Q: May an institution contract with an outside organization for the conduct of a research misconduct proceeding at the institution?

A: Yes, an institution may use the services of a consortium or person that the institution reasonably determines to be qualified by practice and experience to conduct a research misconduct proceeding. A consortium may be a group of institutions, professional organizations, or mixed groups that will conduct research misconduct proceedings for other institutions. A consortium or person acting on behalf of the institution must comply with the final rule and the institution remains responsible for complying with its assurance and the rule. Section 93.306.

Q: May an institution have different standards and definitions for research misconduct than those in the final rule?

A: Yes. Although an institution must apply the regulatory definitions, standards, and requirements in evaluating an allegation of research misconduct reported to ORI, it may also apply its internal definitions or standards in determining whether misconduct has occurred at the institutional level. An institution may find misconduct under its internal standards and impose administrative sanctions based on that finding, regardless of whether the institution or ORI makes a finding of research misconduct under the HHS standard. Section 93.319.

Q: What actions may ORI and HHS take if an institution is deficient in complying, or fails to comply with its assurance and the requirements of the final rule?

A: ORI may address institutional deficiencies through technical assistance if the deficiencies do not substantially affect compliance with the final rule. If an institution fails to comply with its assurance and the requirements of the final rule HHS may take some or all of the following compliance actions: (1) issue a letter of reprimand; (2) direct that research misconduct proceedings be handled by HHS; (3) place the institution on special review status; (4) place information about the institutional noncompliance on the ORI web site; (5) require the institution to take corrective actions; (6) require the institution to adopt and implement an institutional integrity agreement; (7) debar or suspend the institution; and (8) any other action appropriate to the circumstances.

Q: What does ORI consider in making decisions on institutional noncompliance?

A: ORI may decide that an institution is not compliant with the final rule if it shows a disregard for, or inability or unwillingness to implement and follow the requirements of the final rule and its assurance. In making this decision, ORI may consider, but is not limited to the institution's:

- Failure to establish and comply with policies and procedures required by the final rule.
- The existence of institutional policies and procedures that conflict with, or substantially impede compliance with, requirements of the final rule.
- Failure to respond appropriately when allegations of research misconduct arise.
- Failure to report to ORI all investigations, admissions, findings of misconduct, and proposed settlements at any stage of the process in compliance with the final rule.
- Failure to cooperate with ORI's review of research misconduct proceedings.
- Acts or omissions that have a material, adverse effect on reporting and responding to allegations of research misconduct. Section 93.412.

Reporting

Q: In summary, what must institutions report or submit to ORI?

A:

- An annual report containing the information specified by ORI on the institution's compliance with the final rule. Section 93.302(b).
- A Small Organization Statement, if the institution believes it is too small to handle research misconduct proceedings. Section 93.303.

- Within 30 days of finding that an investigation is warranted, the written finding of the responsible official and a copy of the inquiry report. Sections 93.304(d), 93.309(a), and 93.310(a) and (b).
- Where the institution has found that an investigation is warranted, the institution must provide to ORI upon request: (1) the institutional policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges for the investigation to consider. Section 93.309.
- Periodic progress reports, if ORI grants an extension of the time limits on investigations or appeals and directs that such reports be submitted. Sections 93.311(c) and 93.314(c).
- Following completion of the investigation report or any appeal: (1) a copy of the investigation report with all attachments and any appeals; (2) the findings of research misconduct, including who committed the misconduct; (3) a statement of whether the institution accepts the findings of the investigation; and (4) a description of any pending or completed administrative actions against the respondent. Section 93.315.
- Upon request, custody or copies of records relevant to the research misconduct allegation, including research records and evidence. Section 93.317(c).
- Notify ORI immediately of the existence of any of the special circumstances specified in Section 93.318.
- Any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research misconduct or the institution's handling of such an allegation. Section 93.400(b).

Q: What is a “research misconduct proceeding” as defined in the final rule?

A: Any actions related to alleged research misconduct taken under the final rule, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings, and administrative appeals. Section 93.223.

Q: What must an institution report to ORI during the research misconduct proceeding?

A: At any time during the research misconduct proceeding an institution must notify ORI immediately if it has reason to believe any of the following special circumstances exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
- HHS resources or interests are threatened.
- Research activities should be suspended.
- There is a reasonable indication of possible violation of civil or criminal law.
- Federal action is required to protect the interests of those involved in the research misconduct proceeding.
- The research misconduct proceeding may be made public prematurely.

- The research community or public should be informed. Section 93.318

Respondents, Complainants, Witnesses and PHS funded Researchers

Q: What information must institutions provide to PHS funded researchers?

A: The institution must inform researchers involved with PHS supported biomedical or behavioral research, research training or activities related to that research or research training, including those applying for PHS support, about the institutional policies and procedures for responding to allegations of research misconduct, and the institution's commitment to compliance with those policies and procedures. Section 93.302(a)(2)(i).

Q: What information and opportunities must an institution provide to a respondent in the course of a research misconduct proceeding?

A: The institution must:

- Make a good faith effort to notify the respondent in writing at the time of or before beginning an inquiry. Sections 93.304(c), 93.307(b).
- Provide the respondent an opportunity to comment on the inquiry report and attach to the report any comments from the respondent. Sections 93.304(e), 93.307(f).
- Notify the respondent of the outcome of the inquiry. The notice must include a copy of the inquiry report and include a copy of, or refer to, the final rule and the institution's policies and procedures. Section 93.308(a).
- Within a reasonable amount of time after determining that an investigation is warranted, but before the investigation begins (the investigation must begin within 30 days after the determination that it is warranted), notify the respondent in writing of the allegations to be investigated. The institution must give the respondent written notice of any new allegations within a reasonable time after deciding to pursue allegations not addressed in the inquiry or in the initial notice of investigation. Section 93.310(c).
- Interview the respondent during the investigation, provide the recording or transcript to the respondent for correction, and include it in the record of the investigation. Section 93.310(g).
- Interview during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, provide the recording or transcript to the witness for correction, and include it in the record of investigation. Section 93.310(g).
- Give the respondent a copy of the draft investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based. Any comments must be submitted within 30 days of the date on which the respondent received the draft report and must be considered by the institution and included in the final report. Sections 93.304(f), 93.312(a).

Q: Does a respondent have a right to continue his/her research after allegations of research misconduct have been made?

A: The final rule does not address this issue directly. Section 93.305 requires the institution to: (1) promptly obtain custody of and sequester all research records and evidence needed to conduct the research misconduct proceeding; and (2) where appropriate, give the respondent copies of, or reasonable, supervised access to the research records. There are at least two

reasons for providing such access: to enable the respondent to prepare a defense against the allegation; and/or to continue the research.

The determination of when it would be inappropriate to provide respondent copies of or access to the research records is left to the discretion of the institution. In exercising this discretion, institutions should consider separately the issues of whether the respondent should continue the research and whether and under what circumstances the respondent should be given copies of or access to the research records. In considering the former issue, institutions should weigh, among other factors, the special circumstances listed in Section 93.318, the importance of continuing the research, and whether the expertise of the respondent is unique. Institutions must also be cognizant of the interests of the PHS funding agency and the need to confer with that agency about suspension or discontinuation of the research or to obtain approval if the Principal Investigator is being replaced. If the respondent does not continue the research, he or she would still have the right of reasonable, supervised access to the records for the purpose of preparing a defense to the allegation. In order to ensure that the respondent has this opportunity at the investigation stage, Section 93.312(a) requires the institution to give the respondent a copy of, or supervised access to the evidence upon which the draft investigation report is based concurrently with the provision of the draft report for comment by the respondent. Sections 93.305, 93.312(a) and 93.318.

Q:

What opportunities does a respondent have following the institution's finding of research misconduct?

A: The respondent has the opportunity to:

- Participate in any appeal offered under the institution's policies and procedures. Section 93.314(a).
- Admit guilt or seek to settle the case with the institution, but to finally resolve the allegation, the acceptance of such an admission or any proposed settlement must be approved by ORI. Section 93.316.
- Be notified of an ORI finding of research misconduct and proposed HHS administrative actions in an ORI charge letter sent by certified mail or a private delivery service to the respondent's last known address or the last known principal place of business of the respondent's attorney. Section 93.405.
- Admit guilt or seek to settle the case with ORI. Section 93.404.
- Within 30 days of receipt of the charge letter, request a hearing in writing, in accordance with the requirements of Section 93.501.
- If the Administrative Law Judge (ALJ) grants the hearing request, respondent may waive the opportunity for an in-person proceeding and the ALJ may review and decide the case on the basis of the administrative record. Sections 93.503(d) and 93.511(b)(3).
- During the hearing, the rights afforded to the parties under Section 93.505.

Q: **What is the role of a person who alleges research misconduct under the new regulation?**

A: The new regulation uses a new term, "complainant," defined as a person who in good faith makes an allegation of research misconduct. The role of the complainant is limited. Once the complainant has made an allegation of research misconduct, that person does not participate

in the proceeding other than as a witness. A complainant is not the equivalent of a “party” in a private dispute. In conformance with the OSTP policy, the HHS internal review group, and current agency practice, an institution has an obligation to pursue allegations of research misconduct independent of the complainant’s role. Sections 93.203, 93.300(b), and 93.307(a).

Q: What interactions does an institution have with the complainant in the course of a research misconduct proceeding?

A: The institution:

- May notify the complainant whether the inquiry found an investigation to be warranted and provide relevant portions of the inquiry report to the complainant for comment. Section 93.308(b).
- Must interview the complainant during the investigation, provide the recording or transcript to the complainant for correction, and include it in the record of investigation. Section 93.310(g).
- May provide the complainant a copy of the draft investigation report or relevant portions of it and, if so, require that comments be submitted within 30 days of the date on which the complainant received the document. Section 93.312(b).
- Must consider any comments made by the complainant on the draft report and include those comments in the final investigation report. Section 93.313(g).

Q: What confidentiality protections must institutions provide respondents and complainants?

A: Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective, and fair research misconduct proceeding and as allowed by law, but the institution must disclose the identity of respondents and complainants to ORI pursuant to an ORI review of the research misconduct proceeding under Section 93.403 and pursuant to other requirements of the final rule. Section 93.108(a).

Research Records and Evidence of Research Misconduct

Q: What is the responsibility of an institution for maintenance and custody of research records and evidence?

A: An institution must:

- Either before or when the institution notifies the respondent of the allegation, inquiry or investigation, promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where scientific instruments shared by a number of users are involved, custody may be limited to copies of the data or evidence from such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.
- Where appropriate, give the respondent copies of, or reasonable, supervised access to the research records.

- Undertake all reasonable and practical efforts to take custody of additional research records or evidence that is discovered during the course of a research misconduct proceeding.
- Maintain the research records, evidence, and other records of the research misconduct proceeding in a secure manner for seven years after completion of the proceeding or any HHS proceeding, whichever is later, unless custody of the records has been transferred to HHS or ORI has notified the institution that it no longer needs to retain the records. Section 93.305.

Inquiries

Q: When must an institution conduct an inquiry?

A: When there is a written or oral statement or other communication to an institutional or HHS official that alleges misconduct in connection with the institution's application for PHS support for biomedical or behavioral research, research training, or activities related to that research or research training, or the institution's PHS supported projects or products of such research, if: (1) the allegation is within the definition of research misconduct in the rule; (2) the rule applies to the allegation under Section 93.102; and (3) the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. Sections 93.201 and 307.

The process of evaluating an allegation to determine if it meets the three criteria listed above is referred to as an allegation assessment. An institution is also required to conduct an allegation assessment if ORI forwards an allegation to the institution for that purpose. If ORI decides that an inquiry is warranted it forwards the matter to the appropriate institution to conduct the inquiry. Section 93.402(a) and (c).

Q: How should institutions deal with bad faith allegations?

A: The handling of bad faith allegations is left to the discretion of the institutions. The final rule does not define "bad faith," but under the definition of "good faith" in Section 93.210, a bad faith allegation is one that the complainant does not believe to be true or whose belief that the allegation is true is unreasonable, based on what a reasonable person in the complainant's position would believe on the basis of information known to the complainant. The definition of "good faith" makes it clear that an allegation can lack sufficient credibility and specificity so that potential evidence of research misconduct cannot be identified (Section 93.307(a)(3)), but not be a bad faith allegation. Thus, if institutions exercise their discretion to address bad faith allegations, fair procedures for determining whether there has been a bad faith allegation should be included. ORI is prepared to work collaboratively with the research community to develop guidance in this area if research institutions and associations desire to do so. Sections 93.210, and 93.307(a)(3).

Q: What is the purpose of an inquiry?

A: To conduct an initial review of the evidence to determine if an investigation is warranted. An investigation is warranted if the following determinations are made:

- There is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and involves PHS supported biomedical or behavioral research, research training, or activities related to that research or research training.
- Preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance. Section 93.307.

Q: What are the requirements for the inquiry report?

A: The report must be in writing and include: (1) the name and position of the respondent, (2) a description of the allegations of research misconduct and a description of the PHS support, including grant or contract numbers, applications and publications listing PHS support; (3) the basis for recommending or not recommending that an investigation is warranted; and (4) any comments the respondent has made on the report after being afforded an opportunity to do so. The inquiry report is to be completed within 60 calendar days of the initiation of the inquiry, but if that deadline is not met the inquiry record must include documentation of the reasons for exceeding the 60-day period. Sections 93.307 and 93.309.

The inquiry report must be provided to the respondent as part of the notification of the results of the inquiry. That notification must also include the institution's research misconduct policies and include a copy of, or refer to the HHS the final rule on research misconduct. Section 93.308.

Q: Does the complainant have a right to comment on, and receive a copy of the inquiry report?

A: No, the final rule does not require the institution to give the complainant an opportunity to comment on the inquiry report or to notify the complainant of the outcome of the inquiry. An institution may provide these opportunities, if it chooses. Section 93.308(b).

Q: Must all inquiry reports be submitted to ORI?

A: No. Inquiry reports that provide the basis for an institutional finding that an investigation is warranted must be submitted to ORI. In addition, the report must be provided to ORI when the inquiry report makes a finding of research misconduct, such as when the respondent makes an admission, or when the institution otherwise proposes to settle the case, in which case ORI must be notified. When ORI has referred the allegation to the institution and has asked for an inquiry report or has otherwise learned of the allegation and requests further information, ORI must also be notified. Where it is concluded that an investigation is not warranted, institutions must keep sufficiently detailed documentation of inquiries to permit a later assessment by ORI of the institution's decision. Consistent with Section 93.317, institutions must retain those records in a secure manner for at least seven years after the termination of the inquiry, unless custody has been transferred to ORI or ORI has advised the institution that the records no longer need to be retained. Upon request, the institution must provide the records to ORI or other authorized HHS personnel. Section 93.309.

Investigations

Q: What are the requirements for reporting to ORI on the decision to initiate an investigation?

A: Within 30 days of finding that an investigation is warranted, the institution must provide ORI with: (1) a written finding by the responsible institutional official; and (2) a copy of the inquiry report.

In addition, the institution must provide the following information to ORI upon request: (1) the institutional policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges for the investigation to consider. Section 93.309.

Q: What are the requirements for the conduct of an investigation?

A: Institutions must:

- Initiation. Begin the investigation within 30 days after determining that it is warranted.

- Notice to ORI. Notify the ORI Director on or before the date the investigation begins.
- Notice to Respondent. Notify the respondent in writing of the allegations before the investigation begins and of any new allegations within a reasonable time after the decision to pursue an allegation that was not addressed in the inquiry or the initial notice of the investigation.
- Custody of the records. To the extent they have not already done so at the allegation or inquiry stages, obtain custody of and sequester in a secure manner all the research records and evidence needed to conduct the research misconduct proceeding. Whenever possible, the institution must: (1) take custody of the records before or at the time the institution notifies the respondent; and (2) whenever additional items become known or relevant to the investigation.
- Documentation. Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegation.
- Fair Investigation. Take reasonable steps to ensure an impartial and unbiased investigation, including participation of individuals with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved in the inquiry or investigation.
- Interviews. Interview each respondent, complainant, and any other available person who has been reasonably identified as having information on relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation.
- Pursue leads. Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion. Section 93.310.
- Completion. Complete all aspects of the investigation, including sending the final report to ORI under Section 93.315, within 120 days of beginning it, unless ORI grants an extension on the basis of the institution's written request. If an extension is granted, ORI may direct the submission of periodic progress reports. Section 93.311.

Q: Must the institution give the respondent and complainant an opportunity to comment on the draft investigation report?

A: Respondent. The institution must give the respondent a copy of the draft report and, concurrently, a copy of, or supervised access to, the evidence on which the report is based. The comments of the respondent on the draft report, if any, must be submitted within 30 days of the date on which respondent received the draft report. Section 93.312(a).

Complainant. The institution has discretion as to whether or not to give the complainant a copy of the draft report or relevant parts of it. The comments of the complainant, if any, must be submitted within 30 days of the date on which the complainant received the draft report for comment. Section 93.312(b).

Q: What must the institutional investigation report contain?

A: The report must include:

- Allegations. Describe the allegations of research misconduct.
- PHS support. Describe and document the PHS support, including grant numbers, grant applications, contracts, and publications listing PHS support.
- Institutional charge. Describe the specific allegations of research misconduct that the institution considered in the investigation.
- Policies and procedures. If not already provided to ORI with the inquiry report, include the institutional policies and procedures under which the investigation was conducted.
- Research records and evidence. Identify and summarize the research records and evidence reviewed, and any evidence taken into custody but not reviewed.
- Statement of findings. For each allegation or research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur and, if so:
 - Identify whether it involved falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;
 - Summarize the facts and analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent;
 - Identify the specific PHS support;
 - Identify any publications that need to be corrected or retracted; and,
 - List any current support or known applications or proposals for support the respondent has pending with non-PHS Federal agencies.
- Comments. Include and consider any comments made by the respondent and complainant on the draft investigation report.
- Maintain and provide records. Maintain and provide to ORI upon request all relevant research records and evidence, including results of all interviews and transcripts or recordings of such interviews. Section 93.313.

Q: Must an institution provide for an appeal from its findings of research misconduct in an investigation?

A: No, but if the institution provides for an appeal that could result in a reversal or modification of the findings of the investigation report, it must complete the appeal within 120 days of its filing or, if unable to complete the appeal within that time period, the institution must request an extension in writing from ORI and provide an explanation for the request. ORI may grant extensions for good cause and, if an extension is granted, direct the institution to submit periodic progress reports. This time period does not apply to institutional termination proceedings. Section 93.314.

Q: What must an institution provide to ORI after an investigation and any appeal has resulted in a final finding of research misconduct?

A: (1) The investigation report, including all attachments and any appeals.

(2) A statement of whether the institution found research misconduct, and, if so, who committed the misconduct.

(3) A statement of whether the institution accepts the findings of the investigation.

(4) A description of any pending or completed administrative actions against the respondent. Section 93.315.

Settling and Closing Cases

Q: Does the new regulation permit the current practice of resolving cases of research misconduct through settlement agreements?

A: Yes. HHS may settle a research misconduct proceeding at any time it concludes that settlement is in the best interests of the Federal Government and the public health or welfare. Settlement agreements are publicly available, regardless of whether ORI makes a finding of research misconduct. Section 93.409.

Q: May an institution close a case at the inquiry, investigation, or institutional appeal stage (e.g., admission of guilt or proposed settlement)?

A: Yes, but it must notify ORI in advance of any planned closure, including any proposed settlement with the respondent, except for the closing of a case after the inquiry on the basis that an investigation is not warranted or a finding of no misconduct after completion of an investigation or appeal, which nevertheless must be reported to ORI under Section 93.315. Many institutions contact ORI in advance when they are considering settlement. Sometimes ORI, the institution, and the respondent will join in a three-way agreement settling the proceeding. Any settlement action undertaken by the institution, without prior ORI approval, which contravenes the regulatory requirements may result in an ORI compliance action.

After consulting with the institution on its basis for closing a case, ORI may conduct an oversight review and take appropriate action including: (1) approving or conditionally approving closure of the case; (2) directing the institution to complete its process; (3) referring the matter for further investigation by HHS; or (4) taking compliance action. Section 93.316.

Authorities of ORI and HHS

Q: What does ORI do when it receives the institution's final finding of research misconduct?

A: ORI reviews the institution's research misconduct proceedings. In conducting this review, ORI may:

- Determine whether there is HHS jurisdiction under the final rule.
- Consider any reports, institutional findings, research records, and evidence.
- Determine if the institution conducted the proceedings in accordance with the final rule, in a timely and fair manner, and with sufficient expertise, thoroughness, objectivity, and competence to support the conclusions.
- Obtain additional information or materials from the institution, the respondent, complainant, or other persons or sources.
- Conduct additional analyses and develop the evidence.
- Decide whether research misconduct occurred, and, if so, who committed it.

- Make appropriate research misconduct findings and take any other actions necessary to complete the review. Section 93.403.

Q: What does ORI do after completing its review of the institution's research misconduct proceeding?

A: After completing its review, ORI may:

- Close the case if ORI decides that research misconduct did not occur.
- Make findings of research misconduct and make settlement recommendations to HHS.
- Propose and obtain HHS approval of administrative actions based upon the institution's records and any other information obtained during the ORI review. Section 93.404.
- Upon receiving HHS approval of the administrative actions, send a charge letter by certified mail or private delivery service to the last known address of respondent or the last known principal place of business of the respondent's attorney. (If debarment or suspension from eligibility for federal financial assistance is proposed, the HHS debarring official issues the notice for that action as part of the charge letter.) Section 93.405.

Q: What administrative actions may HHS impose as part of a settlement or propose in a charge letter to the respondent?

A: The administrative actions include:

- Return the case to the institution for additional proceedings necessary to comply with the requirements of the final rule.
- Correction or retraction of the research record.
- Letters of reprimand.
- Imposition of special certification or assurance requirements to ensure compliance with applicable regulations or terms of PHS funding awards.
- Suspension or termination of a PHS funding award.
- Restriction on specific activities or expenditures under an active PHS funding award.
- Special review of all requests for PHS funding.
- Imposition of supervision requirements as part of the terms of a PHS funding award.
- Certification of attribution or authenticity in all requests for support and reports to the PHS.
- No participation in any advisory capacity to the PHS.
- Suspension or debarment under 45 CFR Part 76, 48 CFR Subparts 9.4 and 309.4, or both.
- If the respondent is a Federal employee, adverse personnel action in compliance with relevant Federal personnel laws and policies.

- Recovery of PHS funds spent in support of the activities that involved research misconduct. Section 93.407.

Q: What mitigating and aggravating factors will HHS consider in proposing and imposing administrative actions?

A: The purpose of HHS administrative actions is remedial. The appropriate administrative action is commensurate with the seriousness of the misconduct, and the need to protect the health and safety of the public, promote the integrity of the PHS supported research and research process, and conserve public funds. In determining appropriate administrative actions and their terms, HHS considers the following factors as appropriate in each case:

- Were the respondent's actions knowing or intentional, or was the conduct reckless?
- Was the research misconduct an isolated event or part of a continuing or prior pattern of dishonest conduct?
- Did the misconduct have a significant impact on the proposed or reported research record, research subjects, other researchers, institutions, or the public health or welfare?
- Has the respondent accepted responsibility for the misconduct by: (1) Admitting the conduct? (2) Cooperating with the research misconduct proceeding? (3) Demonstrating remorse and awareness of the significance and seriousness of the research misconduct? and, (4) Taking steps to correct or prevent the recurrence of the research misconduct?
- Does the respondent blame others rather than accepting responsibility for the actions?
- Did the respondent retaliate against complainants, witnesses, committee members, or other persons?
- Is the respondent presently responsible to conduct PHS supported research?
- Are there other factors appropriate to the circumstances of the particular case?

Q: When does the ORI finding of research misconduct and the proposed HHS administrative actions become final?

A:

- If the respondent does not contest the charge letter by requesting a hearing within the 30-day period prescribed in Section 93.501, the finding of research misconduct becomes final and the proposed administrative actions become final and will be implemented, except that the debarring official's decision is the final HHS action on any proposed debarment or suspension. Section 93.407.
- Upon the approval by both parties of a settlement agreement containing the findings and the administrative actions (settlement agreements are publicly available). Section 93.409.
- If the request for a hearing is granted, the proposed findings of fact and conclusions of law of the Administrative Law Judge (ALJ) become the final HHS action on all matters except a proposed debarment or suspension, if the Assistant Secretary for Health (ASH) does not notify the parties of an intention to review the ALJ's recommended decision within 30 days after service of that decision upon the ASH. Section 93.523(b).

- If the request for a hearing is granted, and the ASH reviews the ALJ's recommended decision and modifies or rejects it in whole or in part on the basis that it is arbitrary and capricious or clearly erroneous, the decision of the ASH is the final HHS action, if the debarring official concurs with the ASH decision. Section 93.523(b).

- The decision of the ALJ, as it may be modified by the ASH, shall constitute findings of fact to the debarring official and the debarring official's decision on the debarment or suspension is the final HHS action on those administrative actions. Section 93.523(c).

Q: What notification of the final HHS action does the respondent receive?

A: Normally, ORI will notify the respondent in writing. Sections 93.409 and 93.410.

Q: When may ORI respond to an allegation of research misconduct?

A: ORI may respond directly to any allegation of research misconduct at any time, including before, during, or after an institution's response to the matter. The ORI response may include, but is not limited to:

- Conducting an allegation assessment, including determining independently if jurisdiction exists under the final rule. If ORI decides that an inquiry or institutional assessment is not warranted, it will close the case and, where the allegation is not within the jurisdiction of the final rule, forward the allegation to the appropriate HHS component, Federal or State agency, institution or other appropriate entity.

- Forwarding allegations of research misconduct to the appropriate institution or HHS component for an allegation assessment, inquiry, or investigation.

- Recommending that HHS should perform an inquiry or investigation or issue findings and take all appropriate actions in response to the inquiry, investigation, or findings.

- Notifying or requesting assistance and information from PHS funding components or other affected Federal and state offices and agencies or institutions.

- Reviewing an institution's findings and process.

- Making a finding of research misconduct.

- Proposing administrative actions to HHS. Sections 93.400 and 93.402.

Hearing Process

Q: Does the final rule prescribe a formal hearing process for reviewing ORI findings of research misconduct?

A: Yes. The hearing process is modeled upon the current regulation, at 42 CFR 1005, governing the Office of Inspector General hearing process for the exclusion of health care providers, with modifications to reflect current practice, knowledge, and experience in research misconduct proceedings. The hearing process has the following key features:

- Administrative Law Judge. The hearing is conducted by a single ALJ appointed from the Departmental Appeals Board (DAB) Administrative Law Judges. This is a change from the current practice of using a panel of three members of the DAB. Section 93.502(a), (c)-(e).

- **Recommended Decision.** The ALJ's findings of fact and conclusions of law constitute a recommended decision to the Assistant Secretary for Health (ASH). Under the final rule, the ASH may let the ALJ's recommended decision stand, or take final agency action, exercising authority to affirm, reverse, or modify the ALJ's recommended decision, if it is found to be arbitrary and capricious, or clearly erroneous. If debarment or suspension from eligibility for Federal financial assistance and/or contracts is proposed, the decision of the ALJ or of the ASH, as the case may be, constitutes proposed findings of fact to the HHS Debarment Official. Section 93.523.

- **Scientist Experts.** The ALJ is authorized to engage an expert in the relevant area of science to advise the ALJ and must employ such an expert, if requested by either party. Section 93.502(b)-(d).

- **De Novo Proceedings.** The final rule codifies the current practice of providing a de novo hearing to consider challenges to the ORI findings of research misconduct and proposed administrative actions. Section 93.517. A respondent is permitted to waive an in-person hearing and have the case decided on the basis of the administrative record. Section 93.503(d).

- **Standardization of Requirements.** The final rule provides more detail on how the hearing process works. The rule includes requirements for the content of the hearing request, time frames for conducting preliminary conferences, discovery, submission of witness lists and exhibits, and the post-hearing process. 42 CFR Part 93, Subpart E

- **Limited Discovery.** Consistent with the Administrative Procedure Act and other HHS hearing procedures, discovery is limited to an exchange of relevant and material documents and other tangible items for inspection and copying. Following discussion at a prehearing conference, the ALJ may order the parties to develop stipulations and admissions of fact. Section 93.512.

Q: When does the new hearing process for respondent appeals from ORI findings of research misconduct and HHS administrative actions become effective?

A: The new hearing process described in Subpart E of the regulation is in effect for any hearing request made after June 16, 2005.

Q: What is the procedure for the appointment of an ALJ?

A: Within 30 days of receiving a request for a hearing, the Chair of the Departmental Appeals Board (DAB), in consultation with the Chief Administrative Law Judge, must designate an ALJ to determine whether the hearing request should be granted, and if so, to make recommended findings in the case after a hearing or review of the administrative record in accordance with the final rule. No ALJ may serve if he or she has any real or apparent conflict of interest, bias, or prejudice that might reasonably impair his or her objectivity in the proceeding. Section 93.502(a) and (c).

Q: What are the grounds for dismissing a hearing request?

A: The ALJ must dismiss a hearing request if the respondent:

- Does not file the request within 30 days after receiving the charge letter.
- Does not raise a genuine dispute over facts or law material to the findings of research misconduct or the proposed administrative actions in the hearing request or any extension to supplement granted by the ALJ under Section 93.501(d).

- Does not raise any issue that may properly be addressed in a hearing.
- Withdraws or abandons the hearing request.
- Fails to provide ORI with notice of the request for a hearing in the form and manner required by Section 93.501. Section 93.504.

Q: Will an in-person hearing always occur after the granting of a hearing request?

A: No. After the request for a hearing is granted, the respondent may waive the opportunity for an in-person hearing and the ALJ may review and decide the case on the basis of the administrative record. The ALJ may grant a respondent's request that the waiver be conditioned upon the opportunity for respondent to file additional pleadings and documentation. ORI may also supplement the administrative record. Sections 93.503(d) and 93.511(b)(3).

In addition, the parties might reach a settlement before or during the hearing or the ALJ may dismiss the hearing request on the motion of a party.

Q: What are the rights of the parties (ORI and the respondent) to the hearing?

A: The parties may:

- Be accompanied, represented, and advised by an attorney.
- Participate in any case-related conference held by the ALJ.
- Conduct discovery of documents and other tangible items.
- Agree to stipulations of fact or law that must be made part of the record.
- File motions in writing before the ALJ.
- Present evidence relevant to the issues at the hearing.
- Present and cross-examine witnesses.
- Present oral arguments.
- Submit written post-hearing briefs, proposed findings of fact and conclusions of law, and reply briefs within reasonable time frames established by the ALJ or agreed upon by the parties.
- Submit materials to the ALJ and other parties under seal, or in redacted form when necessary to protect the confidentiality of information. Section 93.505.

Q: What is the first formal proceeding in the hearing process?

A: The initial prehearing conference which must be scheduled within 30 days of the DAB Chair's assignment of the case. Section 93.511(a).

Q: When is the hearing scheduled?

A: The hearing is normally scheduled during the initial prehearing conference or subsequent prehearing conferences. Section 93.511(b)(8).

Q: When must the final prehearing conference be held?

A: No later than 15 days before the scheduled hearing date, the ALJ must hold a final prehearing conference to resolve to the maximum extent possible all outstanding issues about evidence, witnesses, stipulations, motions and all other matters that may encourage the fair, just, and prompt disposition of the proceedings. Section 93.511(f).

Q: Is the hearing limited to the findings of research misconduct in the initial charge letter received by the respondent?

A: No. The ORI may amend the findings of research misconduct in the initial charge letter up to 30 days before the scheduled hearing. The ALJ may not unreasonably deny a respondent's motion to postpone all or part of the hearing to allow sufficient time to prepare and respond to the amended findings. Section 93.514.

In addition, a hearing is not limited to the findings and evidence set forth in the charge letter or the respondent's request for a hearing. Additional evidence and information may be offered at the hearing by either party during its case-in-chief unless the offered evidence is:

- Privileged, including but not limited to those protected by the attorney-client privilege, attorney-work product doctrine, or Federal law or regulation.
- Otherwise inadmissible under Sections 93.515 (ALJ actions for violating an order or disruptive conduct including prohibiting a party from introducing certain evidence) or 93.519 (ALJ decides the admissibility of evidence at the hearing, subject to the requirements for specific evidence in this section).
- Not offered within the times or terms of Sections 93.512 (discovery) and 93.513 (submission of witness lists, witness statements and exhibits). Section 93.517(c).

Q: Must the respondent appear at the hearing?

A: The respondent may appear at the hearing in person or by an attorney of record in the proceeding, but the respondent must always appear in person to present testimony and for cross-examination. Sections 93.517(f) and 93.518(c).

Q: Is the hearing open to the public?

A: The hearing must be open to the public, unless the ALJ orders otherwise for good cause shown. Even if the hearing is closed to the public, the ALJ may not exclude a party or party representative, persons whose presence a party shows to be essential to the presentation of its case, or expert witnesses. Section 93.517(g).